K121653

1 SECTION 2: 510(K) SUMMARY

DEC 2 7 2012

510(k) SUMMARY
(per 21 CFR §807.92)

INTRABEAM® System with INTRABEAM® Spherical Applicators

General Information

Manufacturer: Carl Zeiss Meditec AG
Carl-Zeiss-Strasse 22
D-73447 Oberkochen
Germany
Est. Reg. No. 9615010

Contact Person: Sarah Harrington, MS, MBA
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Device Name/Classification

Trade/Proprietary name:	INTRABEAM® System with INTRABEAM® Spherical Applicators
Common/Usual Name:	X-ray radiation therapy system
Classification name:	System, Therapeutic, X-ray
Classification:	Class II (21 CFR 892.5900)
Product Code:	JAD

Predicate Devices

Company:	Carl Zeiss Meditec AG
Device:	INTRABEAM® System with INTRABEAM® Spherical Applicators, K992577, K051055
Company:	Hologic, Inc.
Device:	MammoSite Radiation Therapy System, K011690, K091378

Intended Use

The INTRABEAM® System is intended to be used for radiation therapy treatment.

Indications for Use

The INTRABEAM® System is indicated for radiation therapy treatments. The INTRABEAM® Spherical Applicators are indicated for use with the INTRABEAM® System to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.

The INTRABEAM® Spherical Applicators used with the INTRABEAM System are able to deliver a prescribed dose of intraoperative radiation in conjunction with whole breast irradiation, based upon the medical judgment of the physician. The safety and effectiveness of the INTRABEAM System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

Device Description

The INTRABEAM System is a miniature, high-dose rate, low energy X-ray source that emits X-ray radiation intraoperatively for the treatment of cancer at the tumor cavity. The INTRABEAM Spherical applicators are accessories to the INTRABEAM System. The INTRABEAM Spherical Applicators received 510(k) clearance in K992577. There are eight sizes of applicators in a set ranging from 1.5 cm to 5.0 cm in diameter. The INTRABEAM Spherical Applicators have not changed in design or technological characteristics as described in K992577.

TARGIT-A Trial

The modifications to the indications for use are supported by the publication, "Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): an international, prospective, randomized, non-inferiority phase 3 trial", published by Vaidya, Joseph, Tobias et al. The study was published in The Lancet (Lancet 2010; **376**: 71-72). The TARGIT-A trial was designed to test the hypothesis that in selected patients, substituting whole breast radiotherapy after breast-conserving surgery with targeted intraoperative radiotherapy (IORT) to the tumor bed would not lead to inferior local control of breast cancer. The randomly controlled study (N=2,232) was conducted by physicians around the world using the INTRABEAM System with Spherical Applicators as the only abbreviated partial breast irradiation (ABPI) device. The results of the trial demonstrate a non-significant rate of recurrence between the INTRABEAM Spherical Applicators versus whole breast radiation (1.2% versus 0.95%, p=0.41).

The study concluded that IORT treatment using INTRABEAM Spherical Applicators can be used in conjunction with whole breast radiotherapy.

Substantial Equivalence

Similar to the INTRABEAM System, the MammoSite Radiation Therapy System (RTS) provides a means of delivering radiation therapy in a tumor cavity. Both the MammoSite RTS and the INTRABEAM System with INTRABEAM Spherical Applicators are APBI technology and are comparable in target site and clinical usage.

The INTRABEAM Spherical Applicators that are the subject device for this 510(k) are equivalent to the currently marketed INTRABEAM Spherical Applicators in design, material, radiation doses and principles of operation. Based on the predicate devices and on the findings presented in the TARGIT-A trial publication, the INTRABEAM System with INTRABEAM Spherical Applicators is safe and effective with regards to the proposed indications for use.

Summary

As described in this 510(k) summary and based on the findings presented in the TARGIT-A trial publication, the INTRABEAM Spherical Applicators are safe and effective for their indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 27, 2012

Ms. Sarah Harrington
Staff Regulatory Specialist
Carl Zeiss Meditech, Inc.
5160 Hacienda Drive
DUBLIN, CA 94568

Re: K121653
Trade/Device Name: INTRABEAM® System with INTRABEAM® Spherical Applicators
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: December 17, 2012
Received: December 18, 2012

Dear Ms. Harrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121653

Device Name: INTRABEAM® System with INTRABEAM® Spherical Applicators

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Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____